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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,260	07/12/2000	KENGO AKIMOTO	001560-381	7267
7590 02/10/2004 RONALD L GRUDZIECKI BURNS DOANE SWECKER & MATHIS PO BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER MARX, IRENE	
			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,260	AKIMOTO ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-17, 19, 20 and 23-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 13-16 and 23-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 17, 19, 20 and 27-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The amendment filed 12/10/03 is acknowledged. Claims 11, 17, 19-20, and 27-37 are being considered on the merits.

Claims 12, 18, 21 and 22 are cancelled. Claims 1-10, 13-16, and 23-26 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 102

~~The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the~~
basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-12, 17-22 and 27-37 are/remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Totani *et al.* for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the composition of Totani *et al.* is disclosed as having only 71.2% arachidonic acid content compared to 72% as claimed. However, after a careful review of the instant specification, it was not clear where a lipid is disclosed having the claimed property of being "an isolated arachidonic acid-containing microbial lipid containing 72 % by weight or more of arachidonic acid to the total fatty acids". There is a broad disclosure of 70% or more at

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page 4, paragraph 1; 85.8% at page 24 and “as high as 75.1%” at page 25, paragraph 1. Thus, differences between the invention and the reference cannot readily be assessed.

In response to applicant's assertion that the lipid claimed differs from the composition of Totani because the lipid of the claimed invention which is in the form of mainly triglycerides is an edible composition, it is noted that the invention as claimed is directed to an arachidonic acid containing microbial lipid wherein arachidonic acid may constitute 100% of the lipid (72% or more) and wherein eicosapentaenoic acid may be absent (0.5% by weight or less). In addition, the claim designated invention is not directed to an edible composition. But even if it were, there is nothing in Totani *et al.* to preclude the composition from being edible. Therefore, it is deemed that the reference composition reads on the claimed composition.

Regarding the process step limitations, it is noted that there is no clear nexus or correlation between the process steps used in the instant specification to obtain a product having the touted properties and the invention as claimed. The specification suggests that a process of culturing a specific strain of *Mortierella alpina* SAM 2153 under specific process conditions is required to obtain a product having more than 70% arachidonic acid content. However, this is not the product-by-process composition as claimed. Moreover, no differences are apparent between the composition claimed in claims 17, 19, 27, 28-29, and 34-36 and the reference composition.

Furthermore, the compositions are claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Therefore the arguments are without merit and the rejection is maintained.

Claims 11-12, 17-22 and 27-37 are/remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Li *et al* for the reasons as stated in the last Office action and the further reasons below.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to applicant's assertion that the lipid claimed differs from the composition of Li *et al.* because the process of obtaining the concentrate differs from the claimed process, it is noted that the invention as claimed is directed to an arachidonic acid containing microbial lipid wherein arachidonic acid may constitute 100% of the lipid (72% or more) and wherein eicosapentaenoic acid may be absent (0.5% by weight or less). Thus, a composition comprising only arachidonic acid is embraced by the invention as claimed. In addition, the claim designated invention is not directed to an edible composition. But even if it were, there is nothing in Li *et al.* to preclude the composition from being edible. Therefore, it is deemed that the reference composition reads on the claimed composition, particularly since Li *et al.* indicate that the "recovered oil contained arachidonic acid 72.5% w/w (page 138, first full paragraph, 4th line from bottom of paragraph).

In addition, after a careful review of the instant specification, it was not clear where a lipid is disclosed having the claimed property of being "an isolated arachidonic acid-containing microbial lipid containing 72 % by weight or more of arachidonic acid to the total fatty acids". There is a broad disclosure of 70% or more at page 4, paragraph 1; 85.8% at page 24 and "as high as 75.1%" at page 25, paragraph 1. Thus, differences between the invention and the reference cannot readily be assessed.

Regarding the process step limitations, it is noted that there is no clear nexus or correlation between the process steps used in the instant specification to obtain a product having the touted properties and the invention as claimed. The specification suggests that a process of culturing a specific strain of *Mortierella alpina* SAM 2153 under specific process conditions is required to obtain a product having more than 70% arachidonic acid content. However, this is not the product-by-process composition as claimed. Moreover, no differences are apparent between the composition claimed in claims 17, 19, 27, 28-29, and 34-36 and the reference composition.

Furthermore, the compositions are claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process

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claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Therefore the arguments are without merit and the rejection is maintained.

No claim is allowed.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

~~A shortened statutory period for reply to this final action is set to expire THREE~~ MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 571-272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-9000.



Irene Marx
Primary Examiner
Art Unit 1651